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Before the
Federal Communications Commission
Washington, D.C. 20554

In the Matter of	)	
	)	
Respironics, Inc. and Boston Scientific Corporation	)	ET Docket No. 05-331
	)	
Requests for Waiver of Section 15.205 of the Commission's Rules to Permit the Marketing and Operation of Certain Medical Communications Devices that Operate in the 90-110 kHz Band	)	

ORDER

Adopted: July 11, 2007 **Released: July 11, 2007**

By the Chief, Office of Engineering and Technology:

I. INTRODUCTION

1. By this action, we grant in part a petition for reconsideration seeking modification of a waiver regarding certain medical communications devices produced by Boston Scientific Corporation (Boston Scientific) that are not in compliance with the "restricted band" provisions in Section 15.205 of the Commission's rules.[1] Specifically, we are modifying the waiver to permit Boston Scientific to continue the manufacture and marketing of its next generation Cognis/Telegen 100 series of devices that will operate in the 90-110 kHz band for three years after Food and Drug Administration ("FDA") approval. We find that this action will benefit the public interest by allowing the marketing of important medical devices pending the development of compliant models of those products without increasing the risk of interference to the services protected by Section 15.205.

II. BACKGROUND

2. Boston Scientific is a worldwide manufacturer of implantable medical devices for cardiac patients, including pacemakers (the "PDM" family), cardioverter defibrillators (the "PD2" family), and cardiac resynchronization therapy devices (the "Contak Renewal TR" family). These devices rely entirely upon inductive coupling to download data from and modify the operational settings of the implanted devices, though a process in which an external "wand" is placed over the patient's chest within inches of the implant to send and receive extremely low level transmissions. Because the "wand" reader devices produce fundamental emissions in the 90-110 kHz restricted band, they violate the restricted band provisions of our rules.[2] On June 6, 2006, Boston Scientific requested a waiver of Section 15.205 of the Commission's rules for a variety of its implantable cardiac devices. Boston Scientific also stated in this

[1] 47 C.F.R. § 15.205. Under Section 15.205 of the Commission's rules for unlicensed radio devices, intentional radiators generally are not permitted to operate in certain sensitive or safety-related frequency bands that are designated as "restricted bands." The restricted bands listed in Section 15.205 are bands employed by radio services that function, as a nature of their operation or use, with extremely low signal levels. These systems may be passive, such as radio astronomy, or active, such as satellite down links.

[2] See n. 1, *supra*.

request that it was in the process of developing "next generation" devices (the "Teligen," "Cognis," and "Ingenio" families) that would also use inductive coupling on frequencies in the 90-110 kHz band, but only to initiate a communications session and as a backup means of data communications. It indicated that these new devices would transmit in the 900 MHz band as their primary means of data transfer. Boston Scientific also submitted that it was intending to develop new product lines that would eliminate inductive coupling in the 90-110 kHz band altogether.

3. In view of these considerations, Boston Scientific requested a two-year waiver for its PDM and PD2 devices and a three-year waiver for its Contak Renewal TR devices while it brings its next generation devices to market. For the next generation Cognis, Teligen and Ingenio devices, Boston Scientific requested a waiver for six years after each device's respective market release following the devices' FDA approval. Such a waiver, it argued, would permit Boston Scientific to exit the band in an orderly manner consistent with the asserted compelling public interest in ensuring the continued availability of these devices. It asserted that the additional time would ensure the new devices' thorough and safe development, including time for the multiyear process of testing and FDA approval, and would provide for the continued adequate availability of replacement devices for cardiac patients across the country.

4. On November 16, 2006, the Chief of the Office of Engineering and Technology (OET), pursuant to delegated authority, issued an *Order* (*Waiver Order*) granting Boston Scientific's requests for waivers of Section 15.205 of the Commission's rules for its cardiac devices.[3] The *Waiver Order* permitted the continued manufacture and marketing of the PDM and PD2 series and Contak Renewal TR series for two and three years, respectively, starting from release of the *Waiver Order*, or until six months after final regulatory approval of their next generation replacement devices, whichever comes first. However, for Boston Scientific's next generation Cognis, Teligen and Ingenio devices, the *Waiver Order* permitted manufacture and marketing for three years after the release date of the *Order* instead of the requested six years from FDA approval.

5. On December 18, 2006, Boston Scientific filed a petition for reconsideration of the *Waiver Order* as it applies to its Cognis and Teligen devices.[4] By this petition, Boston Scientific reasserts its request that the waiver period begin at the time of FDA approval and extend for six years thereafter. Alternatively, it requests that the Commission should at least reconsider the starting date of the waiver. Boston Scientific argues that adjustment of the waiver period for the Cognis and Teligen series of devices is appropriate because 1) the devices pose no adverse impact to licensed users of the band, 2) implantable cardiac devices are complex to design and test and, therefore, there can be no assurance that the re-design process can reliably be completed in three years, and 3) the devices are subject to a lengthy FDA approval cycle, which could exceed the Commission's waiver grant or extend so far into the grant as to leave insufficient time to manufacture and market such devices. Boston Scientific further states that, due to unanticipated delays in product development, it does not plan to submit the first implants in the Cognis and Teligen series for FDA approval until late 2007 – with final approval not expected until sometime during 2008, or later. As a result, Boston Scientific claims, it anticipates a timeline in which the current three-year waiver period would likely end within only a few months of the devices being brought to market. Such a result, it asserts, would render the existing waiver for the Cognis and Teligen series all but meaningless.

[3] *See In the Matter of Respironics, Inc. and Boston Scientific Corporation, Requests for Waiver of Section 15.205 of the Commission's Rules to Permit the marketing and operation of certain medical communications devices that operate in the 90-110 kHz band*, 21 FCC Rcd 13450, *Order*, ET Docket No. 05-331 (2006) (*Waiver Order*). The Respironics waiver is not at issue here.

[4] *See Petition for Reconsideration*, filed on December 18, 2006. The petition does not extend to Boston Scientific's Ingenio family of devices, which were included with its original waiver petition. (*See* n.1 therein (stating that Boston Scientific was evaluating whether a waiver would be needed for these devices).)

III. DISCUSSION

6. The underlying intent of the *Waiver Order* was to provide a reasonable period of time for the manufacture and marketing of the transitional Cognis and Teligen devices in anticipation of Boston Scientific's introduction of fully compliant models. This conclusion is supported by the finding in the *Waiver Order* that Boston Scientific's next generation devices, including the Cognis and Teligen series, would fill an important gap until fully compliant products are introduced, and would pose significantly less interference potential to the services protected by Section 15.205 than its medical implant devices currently operating in the 90-110 kHz band.[5] Among other beneficial considerations, OET observed that transitional devices will include improved technology and design to improve performance and enhance patient safety.

7. However, as Boston Scientific advises us in its instant petition, these new fully compliant devices are still under development and must subsequently receive FDA approval before they can be marketed. We agree with Boston Scientific's assertion that the intent of the waiver would be substantially frustrated if the waiver expires shortly before or after FDA approval. Moreover, we are mindful of the possible adverse consequences of short-term product shortages if these next generation devices were not to be available for a reasonable phase-out period.[6] Such shortages would be detrimental to the public, and specifically to medical patients and their families who benefit from their use.

8. Therefore, because of the important transitional role that will be served by these devices in supporting medical needs, we determine upon reconsideration that there is good cause for modifying the start date of the waiver for the Cognis and Teligen devices and that it is in the public interest to do so.[7] We conclude that a start date commencing with FDA approval and running for a period of three years thereafter will provide an adequate period of time for the manufacture and marketing of these devices in expectation of fully compliant models becoming available.[8] Boston Scientific shall provide the date of final FDA approval to the Commission in connection with its application for equipment certification.[9] At the same time, we do not believe that an open-ended waiver is appropriate or should be necessary, and are putting an outer limit on the additional time provided, as specified in the ordering clause, below.

9. In reaching this decision, we decline to accept the six-years-from-FDA-approval formulation requested by Boston Scientific. As expressed in the *Waiver Order*, we are concerned about granting a waiver that could run for an excessive period of time. We thus limit the relief we afford Boston Scientific, while still ensuring a reasonable phase-out period for its next generation devices. As previously stated in the *Waiver Order*, we are not persuaded that the market could not adjust to accommodate Boston Scientific's patients, if necessary, over a shorter time period than the six years Boston Scientific has requested.[10]

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[5] *See Waiver Order* at para. 11.

[6] Boston Scientific also asserted in its waiver request that it supplies 30 percent of all cardiac devices in the U.S., and that taking its product off the market would result in a shortage of such products available for patients that need them, and also reduce market competition in the field.

[7] *See WAIT Radio v. FCC*, 459 F.2d 1203, 1207 (D.C. Cir. 1972); *Northeast Cellular Telephone Co. v FCC*, 897 F2.d 1164 (D.C. Cir 1990).

[8] Any Cognis or Teligen device implanted in a patient during the waiver period will be grandfathered and may continue to operate for its full normal life expectancy; even if that should extend beyond expiration of the waiver.

[9] We note that Boston Scientific had proposed to notify the Commission within writing within 10 business days of its receipt of FDA approval.

[10] We note that Boston Scientific intimated in the conclusion of its petition for reconsideration that a three-year period is at least minimally adequate by clearly implying that the start date is the most important element of its

(continued....)

10. Finally, we emphasize that the basis of our decision herein derives from the central theme expressed in the *Waiver Order*, namely that the waivers at issue present an unusual and compelling public interest situation in which patients and their caregivers rely upon these health- and life-critical technologies. Thus, while Boston Scientific mentions product development delays in seeking reconsideration, we also note that such internal business matters would normally bear little relation to the more relevant question of whether a particular waiver would serve the public interest. Under the unusual circumstances described here, however, we find overriding public interest justification for our decision. Thus, we are acting on the side of caution in finding good cause to provide a reasonable period of time during which patients may benefit from the availability of these important health- and life-critical medical implant technologies.

V. ORDERING CLAUSES

14. Accordingly, pursuant to Sections 4(i), 302, 303(e), 303(r) and 405 of the Communications Act of 1934, as amended (47 U.S.C. §§ 154(i), 302, 303(e), 303(r) and 405), and Section 1.106(a)(1) of the Commission's rules (47 C.F.R. § 1.106(a)(1)), IT IS ORDERED that, if Boston Scientific submits the devices for FDA approval on or before March 31, 2008, the waiver permitting the manufacture and marketing of Boston Scientific's Cognis and Teligen devices is modified to start with the date of FDA approval for the first device in each device series, respectively, and shall continue for three years thereafter for each device series. If Boston Scientific does not meet the March 31, 2008 deadline for filing for FDA approval, the waiver permitting the manufacture and marketing of Boston Scientific's Cognis and Teligen devices is modified to start January 31, 2009, regardless of whether the FDA has approved the devices by that date. Boston Scientific will notify the FCC in writing of its satisfaction of this commitment by the earlier of (a) ten business days after the date on which it submits the devices for approval or (b) April 15, 2008.

15. It is FURTHER ORDERED that Boston Scientific MUST SHOW that it has obtained FDA approval, including date of such approval, as part of its submission for equipment certification of Cognis and Teligen devices.

FEDERAL COMMUNICATIONS COMMISSION

Julius P. Knapp, Chief
Office of Engineering and Technology

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waiver request. ("The Commission should at least reconsider the date on which the waiver period should begin." Petition at 5.)